

**Remarks**

**35 U.S.C. 112, first Paragraph**

Claims 1-4 have been rejected as allegedly unpatentable under 35 U.S.C. § 112, first paragraph, as being non-enabled for the prevention of breast cancer. The Examiner asserts that the utility of breast cancer prevention “is not believable on its face” and further states that “there is no known art where a certain compound is administered to successfully prevent breast cancer.”

Applicants respectfully disagree because the compound tamoxifen citrate is presently approved by the FDA and is indicated for “Reduction in Breast Cancer Incidence in High Risk Women.” Attached is a copy of the package insert for tamoxifen citrate (sold as Novadex<sup>®</sup> by Astrazeneca Pharmaceuticals LP). Page 10 of the package insert sets forth the details of the human clinical trial that was run to gain the approval of the prevention of breast cancer indication by the FDA, and page 16 contains a list of the indications for which tamoxifen citrate is approved, which list includes the prevention of breast cancer.

Furthermore, the prevention of breast cancer is well known to those skilled in the art, and therefore, the prevention of breast cancer is a credible utility. To illustrate the knowledge of those skilled in the art, attached are two documents printed from the web site of the National Cancer Institute. The first document titled “Cancer Facts” highlights the breast cancer prevention studies that are presently being conducted and discusses the prevention of breast cancer. The second document titled Clinical Trials (PDQ<sup>®</sup>) contains the details of a clinical study that is presently being conducted on the prevention of breast cancer using raloxifene hydrochloride, which is marketed as Evista<sup>®</sup> by Eli Lilly and Company. Thus, the prevention of breast cancer is well known to those skilled in the art and is not an incredible utility.

Last, both tamoxifen citrate and raloxifene hydrochloride are estrogen receptor modulators. The compounds of the present claims are also estrogen receptor modulators having different chemical structures from tamoxifen citrate and raloxifene hydrochloride. Thus, that an estrogen receptor modulator could be used for the prevention of breast cancer is a credible assertion for an estrogen receptor modulator.

Because the prevention of breast cancer is well known to those skilled in the art, applicants believe that the utility of the presently claimed invention is credible and withdraw of this rejection is respectfully requested.

Applicants believe that, in view of the remarks made above, this application is in condition for allowance. Reconsideration and allowance of claims 1-4 is respectfully requested.

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